6 telling traits of a CDMO experienced in Annex 1 compliance

GRAND RIVER
ASEPTIC MANUFACTURING

1. Timing

Built With Annex 1 in mind

- Draft Annex 1 documents were considered during design phase
- Followed Annex 1 through build of filling and finishing facilities
- Equipment and technology purchased in line with requirements

2. Equipment

Built for Flexibility

- All filling lines include isolator technology
- Automated lyophilizer loader/unloader within isolator technology
- Single-Use based systems are a platform offering
- PUPSIT ready in all filling and formulation suites

3. Gap Analysis

Identified Gaps

- Department heads assigned to each section
- Internal documents listed for reference
- Formalized assessment report
- Compare client feedback to CDMO processes and QbD

4. CCS

Continuous Improvement

- Established contamination control strategy (CCS)
- CCS is built into systems and policies
- CCS is updated and assessed regularly
- Multi-product facility risk assessment is included

5. Design

Facility Design

- Unidirectional flow for personnel into and out of formulation suites
- Bag-In/Bag-Out High-Efficiency Filtration System
- Large viewing windows and dedicated customer office
- Personnel and Material Flows

6. Resilience

Built to Last

- Regular client audits continuously challenge the process.
- Training developed according to Annex 1 guidelines
- Highest compliance standards are reflected in regulatory history
- Annex 1 release did not result in major changes because CDMO was already acting on the guidelines as they were available

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